JAN 22 2009

Konan Medical Inc

Konan KSS-400 Image Storage System

510(k) Submission

510k number:
K081797

510(k) Summary

(1) Submitter Information

Name Konan Medical Inc

Address 10-29 Miyanishi-Cho

Nishimomiya

662 Japan

Telephone Number 011-81-798-36-3456

Contact Person Dr George Myers (Official Correspondent)

Medsys Inc

377 Rt 17 S

Hasbrouck Heights, NJ 07604

201-727-1703

Date Prepared January 16, 2009

(2) Name of Device

Trade Name Konan KSS-400 Image Storage System

Common Name Computer system for analysis of specular microscope images

Classification Name System, Image management, Ophthalmic

(3) Equivalent legally-marketed devices

Konan Noncon Robo Pachy, K980357

SNT Image Processing System, K992354

Konan Noncon Robo F&A Specular Microscope, K062763

(4) Description

The KSS 400 Image Storage System is a software product that permits users to analyze corneal images made by Konan specular microscopes in a separate computer and to store them in the computer's memory

(5) Intended Use

The KSS-400 Image Storage System is a software product intended to be used for automatic image analysis and data storage for corneal images taken with Specular Microscopes The program analyzes cell density, coefficient of variation, and hexagonality using images taken by the specular microscopes "

(6) Technological characteristics

The KSS-400 is a software product, to be used with the purchaser's own Personal Computer

(b) Performance data

(1) Non-clinical tests

The software has been extensively validated and tested

(2) Clinical tests

Extensive clinical tests were performed for this system as part of the clearance of one of the predicate devices

(3) Conclusions

The Konan KSS 400 is equivalent in safety and efficacy to the legally marketed predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Konan Medical, Inc
c/o George H Myers, Sc D
Medsys, Inc
377 Route 17 South
Hasbrouck Heights, NJ 07604

JAN 22 2009

Re K081797
Trade/Device Name Konan KSS-400 Image Storage System
Regulation Number 21 CFR 892 2050
Regulation Name Picture archiving and communications system
Regulatory Class Class II
Product Code NFJ, NQE
Dated January 7, 2009
Received January 8, 2009

Dear Dr Myers

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

M. B. Eydelman, MD

Malvina B Eydelman, M D
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K081797

Device Name KSS-400 Image Storage System

Indications for Use

"The KSS-400 Image Storage System is a software product intended to be used for automatic image analysis and data storage for corneal images taken with Specular Microscopes The program analyzes cell density, coefficient of variation, and hexagonality using images taken by the specular microscopes "

Prescription Use X OR Over-the-Counter Use

(Per 21 CFR 810 109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K081797